

4. 510(k) SUMMARY

510(k) SUMMARY [as required by section 807.92(c)]

510(k) Owner's Name: Vertebral Technologies, Inc.

Address: 5909 Baker Road, Suite 550
Minnetonka, MN 55345

Phone/Fax/Email: Office – Direct Tel: (952) 979-9357
Company Main Tel: (952) 912-5400
Fax: (952) 912-5410
email: sghai@vti-spine.com

Name of Contact Person: Suresh Ghai, Ph.D.
VP, Quality and Regulatory Affairs

Date prepared: AUG 08, 2013

Trade or Proprietary Name: InterFuse L - Intervertebral Body Fusion Device

Common or Usual Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR § 888.3080
Product code: MAX
Device Class: II

SEP 03 2013

4.1 LEGALLY MARKETING DEVICE TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

The InterFuse L - Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and material to:

1. InterFuse S Intervertebral Body Fusion Device (cleared under Premarket notification # K091988)
2. InterFuse T Intervertebral Body Fusion Device (cleared under Premarket notification # K102277)
3. PrimalIF LLIF Unitary PEEK Lateral Interbody Fusion System (cleared under Premarket notification # K123207)

4.2 DEVICE DESCRIPTION

VTI's InterFuse L - Intervertebral Body Fusion device is made of implant grade Polyetheretherketone (PEEK- OPTIMA[®], Grade LT1), a polymer with a history of use in interbody fusion device designs, and which has a compressive modulus similar to bone. The device has two modules. Module A has a rail and Module B has a slot. The modules are installed by using VTI's proprietary slot riding the rail technology. Both modules have tantalum beads that aid in visualizing the implanted device under X-rays. Each module incorporates a ramp lock to help ensure that it is properly aligned and engaged with the other module. Each module has two vertical slots through the device for the surgeon to fill with autogenous bone that will provide a path for solid bone growth during the fusion process. The device is produced in six heights (7 mm, 8 mm, 9 mm, 10 mm, 12 mm and 14 mm) each for parallel and 8° lordotic configurations to fit the angular geometry of the disc at each disc level. Four anterior – posterior (AP) lengths (16 mm, 18 mm, 21 mm and 24 mm) of the device are being offered. The device will be available in 7 Medial – Lateral (ML) dimensions (35 mm, 40 mm, 45 mm, 50 mm, 55 mm 60 mm and 65 mm).

VTI will supply a set of Instruments (all non-sterile, re-usable manual instruments) for implantation of InterFuse L by a Direct-Lateral Lumbar Interbody Fusion technique.

4.3 INTENDED USE OF THE DEVICE

The InterFuse L - Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse L device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse L device is indicated for use with autogenous bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

4.4 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

InterFuse L Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and materials to InterFuse S Intervertebral Body Fusion Device (cleared under premarket notification # K091988) and InterFuse T Intervertebral Body Fusion Device (cleared under premarket notification # K102277) both products of Vertebral Technologies, Inc.

4.5 SUMMARY AND CONCLUSIONS FROM THE NONCLINICAL TESTS SUBMITTED

The substantial equivalence is supported by bench testing comparing the InterFuse L Intervertebral Body Fusion Device to the predicate devices (K091988 and K102277).

The basic design of the device is similar to the 510(k) cleared predicate devices (K091988 and K102277). The device will be assembled (intra-operatively) via Direct-Lateral Lumbar Interbody Fusion (DLIF) technique as compared to the predicate devices which are

assembled (intra-operatively) via Posterior Lumbar Interbody Fusion and Transforaminal Lumbar Interbody Fusion techniques respectively.

The InterFuse L Intervertebral Body Fusion Device is assembled (intra-operatively) using the same rail and slot system as done for the predicate devices (K091988 and K102277).

The performance of the InterFuse L was tested, post gamma irradiation sterilization, in accordance with ASTM F2077-11 and ASTM F2267 – 04 as detailed below:

- 4.5.1 Device durability was verified by static testing per ASTM F2077-11 for axial load deflection and shear deflection.
- 4.5.2 Device durability was also verified by dynamic testing per ASTM F2077-11 for axial load cyclic fatigue and shear load cyclic fatigue.
- 4.5.3 Subsidence testing was conducted per ASTM F2267-04.

Substantial equivalence comparison between InterFuse L and predicate devices performance results is given in section 10.

The detailed performance results are given in section 12.

The packaged and sterilized InterFuse L device was also tested for cytotoxicity (per ISO 10993-5:2009) and was found to be non-cytotoxic.

The InterFuse L device is sterilized by gamma irradiation by the same process as used for the predicate devices (K091988 and K102277). This process provides a sterility assurance level of 10^{-6} .

On the basis of performance data it is concluded that the InterFuse L – Intervertebral Body Fusion Device is substantially equivalent to the predicate devices (K091988 and K102277).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Vertebral Technologies, Incorporated
% Suresh Ghai, Ph.D.
Vice President, Quality and Regulatory Affairs
5909 Baker Road, Suite 550
Minnetonka, Minnesota 55345 US

September 3, 2013

Re: K131540

Trade/Device Name: Interfuse L- Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 14, 2013
Received: August 15, 2013

Dear Dr. Ghai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. STATEMENT OF INDICATION FOR USE

Indication for Use

510(k) Number (if known): K131540

Device Name: InterFuse L - Intervertebral Body Fusion Device

Indications for Use:

The InterFuse L - Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse L device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse L device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Anton E. Dmitriyev, PhD
Division of Orthopedic Devices